

Questions related to the CAP Vendor Teleconference held July 7, 2005

Additional answers to questions discussed during the teleconference will be posted on the CAP website shortly. Please check the following CAP website <http://www.cms.hhs.gov/providers/drugs/compbid/default.asp> for additional updates.

Also, please note that citations refer to the Interim Final Rule with Comment period published in the Federal Register on July 6, 2006 (70 FR 39022).

Process/administrative Questions

Q. Which quarter of the ASP should be used to determine the composite bid?

A. The 2005 ASP 2nd quarter data should be used to determine the composite bid. The file entitled "April 2005 ASP Pricing File and ASP NOC Pricing File" can be found at <http://www.cms.hhs.gov/providers/drugs/asp.asp>.

Q. What is the address for submitting vendor bid applications?

A. The address for submitting vendor bid applications is:

Centers for Medicare & Medicaid Services
Hospital and Ambulatory Policy Group
Division of Ambulatory Services
Mailstop: C4-01-26
Attention: Capt. Corinne Axelrod
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Q. Where can I obtain the vendor bidding form?

A. The CAP bidding form for vendors and additional related information can be found at the following website:
http://www.cms.hhs.gov/providers/drugs/compbid/bid_form_announ.asp

Q. Can I get a transcript or tape of the vendor call that took place on July 6, 2005?

A. Recordings and transcripts are not available at this time.

Policy Questions

Contracts

Q. Will a CAP vendor have access to each HCPCS price before signing the CAP contract?

A. Qualified vendors will be made aware of the established price set for CAP drugs at the HCPCS level before signing the contract to be an approved CAP vendor.

Q. Can a prospective CAP vendor withdraw its bid prior to signing a contract to supply CAP drugs?

A. Yes, with written notification. Notification should be sent to the following address:

Centers for Medicare & Medicaid Services
Hospital and Ambulatory Policy Group
Division of Ambulatory Services
Mailstop: C4-01-26
Attention: Capt. Corinne Axelrod
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Q. Once a contract has been signed can an approved CAP vendor terminate a contract?

A. As specified in 42 CFR 414.914(a)(2), an approved CAP vendor will be able to terminate the contract if the approved CAP vendor provides notice to us by June 30 for an effective date of termination of December 31 of the same year. We believe that allowing mid-year termination would create unnecessary disruption of the CAP's operation and service. We note that as provided in § 414.914(a), CMS retains the right to terminate or suspend the vendor's contract at any time for default if the approved CAP vendor violates any term of the contract.

Pricing/bidding of Drugs

Q. Since CAP bidders are required to use the Q2ASP pricing file to bid, will the January pricing reflect the blended bids or will the prices change?

A. The single price for each drug (HCPCS code) will be initially determined on the basis of the median of the bids submitted during the second quarter of calendar year 2005 for that drug. The price of each drug will then be updated to the mid-point of calendar year 2006 PPI (Producer Price Index) for prescription preparations; this is a five quarter increase. The PPI for prescription preparations is released monthly by the Bureau of Labor Statistics, and reflects price changes at the wholesale or manufacturer stage.

Addendum B drugs

Q. Mycophenolic acid (J7518) is included on Addendum B. This drug is an oral immunosuppressive agent commonly dispensed by pharmacies. Was it an oversight that this drug was included as a CAP drug? Or is this an exception to CAP initially being reserved for incident to drugs?

A. As stated in the rule, orally administered immunosuppressive drugs are often dispensed by pharmacies, and not provided incident to a physician's service. The CAP category is limited to injectable drugs. Inclusion of mycophenolic acid (J7518) on

Appendix B was an oversight. We are in the process of correcting the form by removing this item. Bids for mycophenolic acid (J7518) will not be required or accepted.

Q. Will the PPI adjustment be added to the 106% ASP rate for addendum B?

A. Yes, adjustments will be made to the single price for each drug (HCPCS code), as described in 70 FR 39074.

Q. For drugs listed in Addendum B, will the reimbursement be pegged to the second quarter 2005 ASP or will it be updated quarterly?

A. There will be one price for each calendar year, unless the conditions for a mid-year adjustment are met, as specified in §414.906(c)(1)(i) – (iv).

Drug ordering/shipments

Q. Will CMS permit a CAP Vendor to accept an electronic drug order from the Participating CAP Physician, provided that the electronic order includes the data points outlined in the IFC?

A. As stated in 70 FR 39039, where transmission of protected health information via electronic means would be permitted under the HIPAA privacy and security rules, covered entities may do so. Transmission of information must comply with all other applicable laws, such as applicable State pharmacy law.

Local Coverage Decisions

Q. The rule excludes leuprolide from the drug list because some carriers have applied the least costly alternative policy to this drug. If CMS recognizes the concerns associated with the implementation of LCA policies, why is CMS requiring LCA to apply to CAP?

A. Drugs supplied under the CAP are subject to applicable local coverage determinations, including those that include a least costly alternative policy. Nothing in the IFC is intended to disrupt the longstanding ability of contractors to apply a least costly alternative policy under Section 1862(a)(1)(A) of the Social Security Act.

Licensure

Q. Will CMS require a potential vendor to obtain a wholesale distributor license if the entity is already licensed as a pharmacy?

A. As stated in 70 FR 39066, we believe that vendors must operate as distributors in order to participate in the CAP, and we recognize that a natural outgrowth of participating in this program may be that those distributors also will need to be licensed as a pharmacy. Regardless, either the vendor, its sub-contractor under the CAP, or both, must be licensed appropriately by each State to conduct its operations under the CAP. Therefore, an applicant may be required to obtain a license for wholesale drug distribution as well as a pharmacy license if state law requires it.

Q. If so, in the event that a specific state considers a pharmacy license and a wholesale distributor license to be mutually exclusive, and therefore entities are not eligible to hold both licenses in that state, would they be excluded from applying and submitting a bid?

A. We encourage all bidders to clarify the exact details of required licensure with an expert in pharmacy and drug distribution law at the State (District or Territory) level. In a situation where possession of a drug distribution and a pharmacy license is not possible, or in a case where obtaining one of these licenses to cover a portion of a geographic area is not feasible, we encourage the bidder to consider alternative approaches, such as forming a contractual relationship with another entity that is qualified to provide the appropriate additional services. The applicant would not be excluded from submitting a bid for this reason, however, the successful applicant would be required to meet all CAP contractual requirements.

Q. Could an entity that is already licensed as a pharmacy and has a national wholesale distributor capabilities submit a bid to participate as a CAP vendor?

A. Yes, if the entity meets all applicable licensure requirements in each State, District and Territory.

Coinsurance

Q. Currently under Part B, providers are able to verify patient supplemental insurance and/or mechanisms to pay the coinsurance before the time of service. Will CAP Vendors have the same ability as exists currently under Part B to determine source of insurance or payment for coinsurance in addition to confirming coverage based on Medicare policies and Local Coverage Decisions?

A. As described in 70 FR 39041, and in §414.908(a)(3)(v) of the regulation, the Participating CAP physician will be providing information to the approved CAP vendor at the time the CAP drug is ordered to facilitate collection of applicable deductible and coinsurance. Among the information to be provided will be information on any supplemental insurance or Medicaid coverage that the beneficiary may have. When the approved CAP vendor receives this information he or she is free to verify the beneficiary's supplemental insurance or Medicaid coverage information, as long as the process can be completed in a timely fashion so that the drug order can be shipped within specified time frames. However, since the beneficiary is not required to have supplemental insurance coverage or Medicaid as a requirement for their physician to participate in the CAP, even if the beneficiary does not have such coverage the approved CAP vendor will still be required to ship the ordered drug, unless the conditions in §414.914(g) are met relating to a beneficiary's failure to pay cost sharing.